K083081

MAR 4 2009

SECTION 3. 510(K) SUMMARY

3.1 ADMINISTRATIVE INFORMATION

3.1.1 Name and address

Sponsor:
181 Cheshire Lane, Suite 100
Plymouth, MN 55441
Tel: (763) 225-6699
Fax: (763) 225-6694

Contact Person
Sew-Wah Tay, PhD
Regulatory Consultant
18555 37th Ave N,
Plymouth, MN 55446

Tel: 612-801-6782
Fax: 763-208-4465
Email: swtay@libramed.com

Date Prepared: December 24, 2008

3.1.2 Device Name

Trade Name	SecurAcath Catheter
Common Name	Periphery Inserted Central Catheter (PICC)
Classification Name	OKC – implanted subcutaneous securement catheter
Classification	21 CFR 880.5970 Class II
Model	SPK01

3.1.3 Applicant

Applicant's Name:
181 Cheshire Lane, Suite 100
Plymouth, MN 55441
Tel: (763) 225-6699
Fax: (763) 225-6694

3.2 INDICATION FOR USE

The SecurAcath PICC is indicated for short or long term peripheral access to the central venous system. The catheter may be used for intravenous therapy, power injection of contrast media, blood sampling and/or infusion therapy. The maximum recommended infusion rate is 5 ml/sec and the maximum pressure of power injectors may not exceed 300 psi. The SecurAcath PICC includes means to secure the catheter via a subcutaneous anchor below the insertion site.

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3.3 Device Description

The SecurAcath is a single use, sterile, flexible PICC catheter with a useful lengths of up to 55 cm. The length of the catheter has markings at 1 cm interval to allow the user to trim the catheter to the required length. The catheter has a built in subcutaneous securement mechanism to stabilize and keep the catheter in place. The catheter has two lumens which are identical in properties and characteristics.

The device is compatible with all 0.018" and smaller guidewires. The proximal end of the catheter has the standard radiology PICC configuration plus the activation mechanism of the securement system built into the Y-body. The catheter has been tested to be compatible with MRI (MR conditional) and use with power contrast injectors.

3.4 Substantial Equivalence

The SecurAcath Catheter device covered by this submission is substantially equivalent to the Interrad Medical SecurAcath K082047 and Bard PowerPICC K051672

The SecurAcath™ has the same indication for use, same principles of operation, and similar technological characteristics as the previously cleared predicate devices. The differences between this device and its predicate devices do not raise new questions of safety or efficacy.

3.5 Performance Data

The performance test data is provided in the 510(k) submission. The performance data demonstrates that the device meets all the product specifications. Performance testing included, biocompatibility testing, dimensional verification; securement reliability, catheter tensile strength and power injection capabilities. Test results demonstrate that the device is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 2009

Interrad Medical, Incorporated
C/o Sew-Wah Tay, Ph.D
Regulatory Consultant
Libra Medical LLC
18555 37th Avenue North
Plymouth, Minnesota 55446

Re: K083081
Trade/Device Name: SecurAcath 5F Dual Lumen PICC 65cm with Subcutaneous Securement System
Regulation Number: 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: OKC
Dated: February 5, 2009
Received: February 6, 2009

Dear Dr. Tay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for

Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K083081

SECTION 2. INDICATION FOR USE STATEMENT

510(k) Number (if known): _K083081_____

Device Name: SecurAcath PICC

Indications for Use:

The SecurAcath PICC is indicated for short or long term peripheral access to the central venous system. The catheter may be used for intravenous therapy, power injection of contrast media, and blood sampling and/or infusion therapy. The maximum recommended infusion rate is 5 ml/sec and the maximum pressure of power injectors may not exceed 300 psi. The SecurAcath PICC includes means to secure the catheter via a subcutaneous anchor below the insertion site.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083081